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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,457	06/13/2001	Christophe Alain Thureau	0537/178002	8829

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Biomeasure Incorporated
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EXAMINER

LIU, HONG

ART UNIT PAPER NUMBER

1624

DATE MAILED: 11/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/719,457

Applicant(s)
Thurleau et al.

Examiner
Hong Liu

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.
- ### Disposition of Claims
- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above, claim(s) 4, 6, 8, 10, 12-21, 25, 26, 29, 31, 32, and 34-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 7, 9, 11, 22, 30, and 33 is/are rejected.
- 7) ☒ Claim(s) 23, 24, 27, and 28 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 6) ☐ Other: _____

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1.

DETAILED ACTION

Claims 1-43 are pending in this application.

Election/Restriction

Applicants' election of Group II subject matter along with method claim 33 with traverse in Paper No. 8 is noted. Some of applicants' traverse is found persuasive. Accordingly, Groups II, III, and IV will be examined together and structure search of R3 will not be limited to indolyl-3-yl. The restriction of other groups is maintained for the following reasons. Restriction is proper when there is a lack of unity of invention and such is not affected by the manner of claiming-i.e. in separate claims or within a single claim. As stated in the previous action the resultant compounds embraced by different bicyclic core constitute structurally dissimilar compounds. Having a common utility among the groups is not enough where as herein there is not a substantial structure feature common to all groups. They are made and used independently of each other, are not art-recognized equivalents. Such traverse of the restriction requirement is not consistent with applicants' urging of patentability over the art cited below which is much closer to some of the claimed compounds than they in turn are to each other. The compounds of WO 98/27108, applied below, which render the compounds of Group II obvious would not have rendered the compounds of other groups obvious since these compounds are only directed to compounds wherein A1 is -C(=Y)-N(X1X2).

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For the above reasons, the restriction is still deemed proper and is therefore made FINAL.

Claims 4, 6, 8, 10, 12-21, 25, 26, 29, 31, 32, and 34-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicants are expected to cancel and amend the non-elected subject matter.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 7, 9, 11, 22, 30, and 33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preparation and use of compounds wherein R1 is hydrogen, does not reasonably provide enablement for preparation and use of compounds wherein R1 is other than hydrogen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The nature of the invention in the instant application has claims which embrace a diversity of chemically and physically distinct compounds, wherein R1 can be, for instance, -(CH₂)-Z1, (C0-C6)alkyl-C(O)-NH-(CH₂)-Z3 wherein Z1 and Z3 can be an unsubstituted or substituted, heteroaromatic group, containing one or more heteroatoms, etc. While many compounds are

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disclosed, there is insufficient guidance for preparing additional "somatostatin receptor antagonists" which would be effective since the cited examples are drawn to a homogenous group of compounds not remotely commensurate in scope to applicants' claims. Only compounds wherein R1 is hydrogen have been made.

Furthermore, testing data is limited to a number of compounds not considered to be representative of all the possible compounds encompassed by the claims. Examples should be of sufficient scope as to justify the scope of the claim. However, the generic claims are much broader in scope than is represented by the testing. The definitions of the various R1 variables embrace many structurally divergent groups not represented at all in testing, since testing for the instant compounds is not seen in the specification. Markush claims must be provided with support in the disclosure when the "working examples" fail to include written description(s) which teach how to make and use Markush members embraced thereby in full, clear and exact terms. See *In re Fouch*, 169 USPQ 429.

This area of activity can be expected to be highly structure specific and unpredictable, as is generally true for chemically-based pharmacological activity. In view of the structural divergence in the claims, one skilled in the art could not reasonably extrapolate the activities of some of the claimed compounds to the other structurally divergent compounds embraced by the claims which have not been tested. In cases directed to chemical compounds which are being used for their physiological activity, the scope of the claims must have a reasonable correlation to the scope of enablement provided by the specification. See *In re Surrey* 151 USPQ 724 regarding sufficiency

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of disclosure for a Markush group. No reasonable assurance has been made that the instant compounds as an entire class have the required activities needed to practice the invention.

Thus, factors such as “sufficient working examples”, “the level of skill in the art” and “predictability” have been demonstrated to be sufficiently lacking in the instant case for the scope being claimed.

Claims 1 and 22 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The scope of “prodrug” is not adequately enabled. Applicants provide no guidance as how the compounds are made more active *in vivo*. The choice of a “prodrug” will vary from drug to drug. Therefore, more than minimal routine experimentation would be required to determine which prodrug will be suitable for the instant invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

3. 1). The term “optionally substituted” throughout claims 1 and 22 is unclear as to the

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nature and number of substituent(s) intended.

2). In claim 1, the phrase "pharmaceutically-acceptable salts" appears twice in the same line, which seems redundant.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 5, 7, 22, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yatabe et al. (Wo 98/27108). Yatabe et al. teach a generic group of amide compounds (See formula I, P. 2), in particular, wherein R1 is anilino, R2 is hydrogen or phenyl alkyl, R4 and R5 are hydrogen, phenyl, imidazole, etc. Compound 27 on page 234 differs from the instantly claimed compounds only in the nature of the position of the substituent on the imidazole ring and thus, is a positional isomer. Thus, one of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. See *In re Susi*, 440 F.2d 442,

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169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. V. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Specification

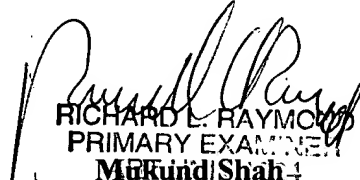
6. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Objections

Claims 23, 24, 27, and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. None of the prior art of record nor a search in the pertinent art area teaches the compounds in these claims.

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual number for **official** business is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

hl
November 2, 2002


RICHARD L. RAYMOND
PRIMARY EXAMINER
~~Mukund Shah~~
Supervisory Patent Examiner
Art Unit 1624